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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,999	06/08/2001	Maxime Ranger	2267.001	1762

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,999

Applicant(s)

Ranger et al

Examiner

Richard Schnizer

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 8, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2, 9 6) ☐ Other:

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DETAILED ACTION

A supplemental IDS was received and entered as Paper No. 9 on 12/23/02)

1. An amendment was received and entered as Paper No. 8 on 12/2/02. Applicant's election with traverse of group I is acknowledged. Traversal is on the grounds that group I is a subcombination and groups II-IV are related as combinations. Applicant's argument rests on the assertion that if the claims of the subcombination were found to be allowable, then it would follow that claims to the combinations would also be allowable. This argument is unpersuasive because the claims characterized by Applicant as combinations are drawn to pharmaceutical formulations whereas the claims characterized as a subcombination are not. Therefore the combination claims are subject to enablement considerations particular to pharmaceutical formulations, and might not be allowable even if free of the prior art. In this case, for example, it is not clear that the specification enables any pharmaceutical formulation comprising genetic material.

For these reasons the restriction requirement is deemed proper and made FINAL.

Claims 15-18 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1-14 are under consideration in this Office Action.

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Claim Objections

2. Claims 2-14 are objected to as ungrammatical. Claim 2 and dependents recite “the group consisting of ionizable or permanently charged repeating units”. A group cannot consist of one species **or** another species, because a species in itself is not a group. The word “and” should be substituted for the word “or” in this context. Similarly, claim 4 requires selection from “the group consisting of a change in pH or conduction of a chemical reaction”. Either the word “and” should be substituted for the word “or”, or the phrase “selected from the group consisting of” should be deleted.

It is noted that the Markush group in claim 1 could be set forth more clearly by rewriting it in outline form. For example “... selected from the group consisting of

- a. diblock copolymers including ionizable and permanently charged units;
- b. multiblock copolymers including ionizable units, permanently charged units, or mixtures of ionizable and permanently charged units;
- and
- c. random copolymers with grafted hydrophilic and essentially non-ionic oligomers or polymers, said random copolymers including ionizable units, permanently charged units, or mixtures of ionizable and permanently charged units,” etc.

At a minimum commas should be inserted between the words “units” and “or” in each instance of the phrase “permanently charged units or”.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-14 are indefinite because it is unclear what is intended by “essentially non-ionic”. The specification fails to define “essentially” in this context, so it is unclear what are the metes and bounds of the claims. It is unclear what amount of ionic character is acceptable.

5. Claims 1-14 are also indefinite because it is unclear what are the metes and bounds of “permanently charged units”. The Examiner is unaware of water soluble molecules comprising electrostatic charges that cannot be neutralized by at least one of adjustment of pH, addition of a salt, or chemical modification (as recited in claim 4). It would seem that any “permanently charged” molecule could be changed to a transiently charged, or uncharged, molecule by an appropriate chemical reaction.

6. Similarly, claims 2-14 are indefinite because it is unclear what is intended by “essentially uncharged” or “essentially hydrophobic”. The specification fails to define “essentially” in these contexts, so it is unclear what are the metes and bounds of the claims. It is unclear what amount of charge or hydrophilic character is acceptable.

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7. Claims 3 and 4 are indefinite because it is unclear what is intended by "external stimulus". Specifically, it is unclear to what the stimulus must be external, so the metes and bounds of the claim are unclear. Deletion from claim 3 of "via an external stimulus" is suggested. Substitution of "transformation to a charged state is caused by" for "said external stimulus is selected from the group consisting of".
8. Similarly, claim 5 is indefinite because it is unclear what is intended by "external conditions". Specifically, it is unclear to what the conditions must be external, so the metes and bounds of the claim are unclear.
9. Claims 7, 8, 11, and 13 are indefinite because it is unclear what are the metes and bounds of the term "derivatives".
10. Claim 8 is indefinite because it recites "said alkyl or aryl derivatives" without proper antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-4 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al (US Patent 5,510,103, issued 4/23/96).

Yokoyama teaches micelles composed of diblock copolymers comprising hydrophilic blocks and blocks comprising ionizable residues and hydrophobic repeating units. In one embodiment of the invention the hydrophilic block is non-ionizable polyoxyethylene, and the ionic block ionizable moiety is an acetic or propionic acid group (see claim 1, especially line 27 wherein R3 may be propionic acid). Propionic acid comprises a hydrophobic segment (ethylene group) that serves as a non-ionic hydrophobic repeating unit. The propionic acid group can be converted between charged and uncharged states by altering the pH of the medium, or by chemical modification, e.g. covalent addition of an uncharged group (see claim 1, lines 30-35. Claim 14 is included in this rejection because it is a product by process in which the claimed product is disclosed in the cited art, rendering the process by which it was made irrelevant.

Thus Yokoyama anticipates the claims.

12. Claims 1-9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Allwohn et al (US Patent 6,372,203, issued 4/16/02).

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Allwohn teaches micellar compositions comprising diblock copolymers of hydrophilic saccharide polymers and polymers of charged monomers comprising hydrophobic repeating units. See column 4, lines 56-59; column 5, lines 24-67; column 6, line 43 to column 7, line 8; and column 10, lines 39-46. In one embodiment the charge can be viewed as permanent, i.e. a quaternary amine (see column 5, lines 34-37. In another embodiment, the charge is subject to pH (secondary and tertiary amines, see column 5, lines 34-37). The hydrophobic repeating units required by the claims can be considered to be the vinyl groups, acrylate derivatives, C1 to C12 alkyl groups, or aryl groups (see column 5, lines 37-55). In one embodiment the copolymer comprising the charged and hydrophobic entities is a polymer of vinyl esters (see column 6, line 64 to column 7, line 8).

Thus Allwohn anticipates the claims.

13. Claims 1-5, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kabanov et al (US Patent 6,440,743, issued 8/27/02).

Kabanov teaches micellar compositions comprising diblock, multiblock, and random graft copolymers comprising a hydrophilic, nonionic polymer and a polycationic polymer with hydrophobic repeating units. See entire document, especially the abstract, column 3, line 30 to column 6, line 64; and column 10, lines 4-49. In one embodiment the charge can be viewed as permanent, i.e. a quaternary amine (see column 10, lines 11 and 12. In another embodiment, the charge is subject to pH (secondary and tertiary amines, see column 10, lines 9 and 10). The

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hydrophobic repeating units required by the claims can be considered to be the ethylene, propylene, butylene, pentylene, or hexylene (see column 10, lines 6-9). The hydrophilic block may comprise acrylamide or acrylamide derivatives.

Summary

Claims 1-14 are under consideration.

Claims 1-14 are rejected under 112, second paragraph as indefinite.

Claims 1-9 and 11-14 are rejected under 35 USC 102 as anticipated by the prior art.

Claim 10 is free of the prior art of record.

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Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.


JEFFREY SIEW
PRIMARY EXAMINER
2/22/03